

Listing of Claims

1. (Cancelled)

2. (Currently amended) A process ~~according to claim 1~~ for making a medicinal vial comprising:

- (1) providing a vial mould having an openable cavity therein defining the shape of a medicinal vial having a mouth opening,
 - (2) moulding a vial in the vial mould cavity using a mouldable medicinally acceptable polymer,
 - (3) opening the vial mould to expose the ~~so-formed~~ vial,
 - (4) removing the ~~so-called~~ vial from the vial mould,
 - (~~6~~5) providing a closure mould having an openable cavity therein defining the shape of a puncturable closure for the mouth opening of the medicinal vial,
 - (~~7~~6) moulding a puncturable closure in the closure mould cavity using a mouldable medicinally acceptable elastomeric polymer,
 - (~~8~~7) opening the closure mould to expose the ~~so-formed~~ puncturable closure,
 - (~~9~~8) removing the ~~so-formed~~ puncturable closure from the closure mould,
 - (~~5~~9) automatically inserting the ~~so-formed~~ puncturable closure into the mouth opening of the ~~so-formed~~ vial,
- and wherein at least steps (3), (4), (~~5~~7), (8) and (9) are performed under sterile conditions.

3. (Currently amended) A process according to claim ~~1~~2 wherein the vial and puncturable closure[[s]] are either or both made by an injection moulding process in which initially solid polymer is fluidised by heat and pressure typically by a helical screw, and is then forced under pressure into the mould cavity.

4. (Currently amended) A process according to claim ~~1~~2 wherein the vial mould cavity is shaped to make a vial having an internally cylindrical tubular shape, with an open end

defining a mouth opening, and an opposite closed end, with a flange externally around the mouth opening.

5. (Currently amended) A process according to claim 12 wherein the vial mould cavity is shaped to make a vial having a closed end with an engagement part suitable for engagement with automatic mechanical handling means.

6. (Currently amended) A process according to claim 12 wherein a cyclo-olefin thermoplastic polymer is used to make the vial.

7. (Currently amended) A process according to claim 12 wherein the closure mould is constructed to make multiples of the numbers of vials made by the vial mould.

8. (Currently amended) A process according to claim 2 wherein steps (4), (58) and (9) are performed by automatic handling means able to releasably engage with the vial and puncturable closure formed in the respective vial and closure moulds, to remove the formed vial and puncturable closure from their moulds, and to bring a vial and closure together to engage a vial with a puncturable closure.

9. (Currently amended) A process according to claim 8 wherein the automatic handling means is configured to releasably engage with plural vials and puncturable closures, to remove plural vials and puncturable closures from their moulds, and to bring plural vials and puncturable closures together to engage plural vials with plural puncturable closures simultaneously.

10. (Currently amended) A process according to claim 8 wherein the automatic handling means engages with the exterior of the closed end of the vial, and engages with a part of the puncturable closure which will not be in contact with the interior of the vial when the puncturable closure is in place.

11. (Currently amended) A process according to claim 8 wherein the automatic handling means releasably engages with the vial or puncturable closure by a suction means that draws the vial or puncturable closure into contact with engaging means of the automatic handling means.

12. (Currently amended) A process according to claim 8 wherein the handling means engaged with a puncturable closure introduces the puncturable closure into a vial in step (59) whilst the vial is also engaged by handling means.

13. (Currently amended) A process according to claim 12 wherein the handling means releases the vial so that the engaged vial and puncturable closure is retained by the handling means engaged with the puncturable closure.

14. (Currently amended) A process according to claim 12 wherein after the assembly of vial and puncturable closure in step (59) the assembly is transferred automatically to a further processing station at which one or more further process is performed on the assembly.

15. (Currently amended) Apparatus for performing a process ~~according to claim 2~~ for making a medicinal vial comprising:

(A) a vial mould having an openable cavity therein defining the shape of a medicinal vial having a mouth opening, and in which a vial may be moulded using a mouldable medicinally acceptable polymer, and which may be opened to expose a vial moulded therein,

(B) a closure mould having an openable cavity therein defining the shape of a closure for a medicinal vial when moulded in the first mould, and in which a closure may be moulded using a mouldable medicinally acceptable polymer, and which may be opened to expose a closure moulded therein,

(C) automatic mechanical handling means adapted to insert a puncturable closure made in the closure mould into the mouth opening of a vial made in the vial mould,

(D) sterilization means to provide a sterile environment in relation to (A), (B) and (C) such that said vial and closure moulds may be opened, a respective vial and closure may be

removed from the respective vial and closure moulds, and the closure inserted into a vial, in the sterile environment.

16. (Original) Apparatus according to claim 15 wherein the vial and closure moulds are both or either injection moulds in which initially solid polymer is fluidised by heat and pressure typically by a helical screw, and is then forced under pressure into the mould cavity.

17. (Previously presented) Apparatus according to claim 15 wherein the vial mould cavity is shaped to make a vial having a closed end with an engagement part suitable for engagement with automatic mechanical handling means.

18. (Previously presented) Apparatus according to claim 15 wherein the closure mould is constructed to make multiples of the numbers of vials made by the vial mould.

19. (Currently amended) Apparatus according to claim 15 provided with automatic handling means able to releasably engage with the vial and closure formed in the respective vial and closure moulds, to remove the formed vial and closure from their moulds, and to bring a vial and closure together to engage a vial with a closure, to ~~perform steps (4), (5) and (9)~~ insert the closure into the mouth opening of the vial.

20. (Original) Apparatus according to claim 19 wherein the automatic handling means is configured to releasably engage with plural vials and closures, to remove plural vials and closures from their moulds, and to bring plural vials and closures together to engage plural vials with plural closures simultaneously.

21. (Currently amended) Apparatus according to claim 19 wherein the automatic handling means is configured to engage with the exterior of the closed end of the vial, and to engage[[s]] with a part of the closure which will not be in contact with the interior of the vial when the closure is in place.

22. (Previously presented) Apparatus according to claim 19 wherein the automatic handling means is configured to releasably engage with the vial or closure by a suction means that draws the vial or closure into contact with engaging means of the automatic handling means.

23. (Currently amended) Apparatus according to claim 19 wherein the handling means is configured to introduce a closure ~~closure~~ engaged by the handling means into a vial in ~~step (5)~~ whilst the vial is also engaged by handling means.

24. (Previously presented) Apparatus according to claim 23 wherein the handling means is configured to release the vial so that the engaged vial and closure is retained by the handling means engaged with the closure.